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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,467	12/04/2001	Keith D. Allen	R-758	7217

26619 7590 12/16/2004

DELTAGEN, INC.  
1031 Bing Street  
San Carlos, CA 94070

EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/005,467

Applicant(s)

ALLEN, KEITH D.

Examiner

Celine X Qian Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 28-47 and 52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-47 and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/4/01 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 28-47 and 52 is pending in the application.

This Office Action is in response to the Amendment filed on 9/27/04.

#### ***Response to Amendment***

Claims 28-47 and 52 stand rejected under 35 U.S.C. 112 1<sup>st</sup> paragraph for reasons set forth of the record mailed on 4/23/04 and further discussed below.

Claim 52 is rejected under 35 U.S.C. 112 2<sup>nd</sup> paragraph for reasons discussed below.

#### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-47 and 52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to this rejection, Applicant argues that the examiner's conclusion regarding the ability of the skilled artisan to use the claimed invention is not consistent with the rules regarding the utility of an invention because the claimed invention has a well established utility. Applicant assert that the skilled in the art would immediately appreciate how to use a knockout mouse because any knockout mouse has the inherent and well-established utility of defining the function and role of the disrupted gene regardless of specific phenotypes, characterizations or

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properties of the knockout mouse. Applicant further cites a passage at NIH website which indicate that knockout mice represent a critical tool in studying gene function. Furthermore, Applicants indicates that the claimed invention is purchased by three largest pharmaceutical companies, thus such commercial acceptance more than satisfied the practical utility requirement of 101 and 112 1<sup>st</sup> paragraph. Moreover, Applicant argues that the claimed knockout mouse is useful for the study of the utility and function of the PTP36 gene and not for the purpose of establishing a utility for the mouse as in the case of *Brenner v. Manson*. Further, Applicant asserts that the examiner has stated that one of ordinary artisan would have been motivated to produce the PTP36 knockout mouse to study the precise role of PTP36 plays in cell growth, adhesion and cytoskeleton in the 103 (a) rejection previously, and such statement is an admission that the skilled artisan would know how to use the claimed invention to determine the function of a gene. Applicant also asserts that the claimed invention is useful for a particular purpose, to further study the role of PTP36 in reproductive system function, or in growth and development in light of the observed phenotypes. Lastly, Applicant argues that the utility of the claimed inventions does not depend on a correlation between the disclosed phenotype and a disease in human for the enablement of the claimed invention. Applicant also argues that the disclosed phenotype is each related to a disorder or condition may be observed in human. Applicant asserts that usefulness in patent law necessarily includes the expectation of further research and development according to *In re Brana*. Applicant thus concludes that the claimed invention is enabled fully by the instant specification.

These arguments have been fully considered but deemed unpersuasive. The reasons for the non-enablement rejection were discussed in detail in the office action mailed on 4/23/04. In

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response to Applicant's response regarding any knockout mouse has a well established utility, the examiner does not agree with Applicant's assertion that the claimed invention has a well established utility. Applicant is reminded that in MPEP, the guideline for the utility requirement clearly states: "An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible." In the instant case, the utility that applies to any knockout mouse is not specific to the claimed invention, the PTP36 knockout mouse. Applicant's assertion that the claimed mouse is useful to study the function of PTP36 is an invitation for further research on the claimed invention in which the function of said invention Applicant clearly does not know.

In response to Applicant's argument of the commercial sale of the claimed mouse, Applicant is reminded that the sale of a product does not automatically gives the product patentable use according to the statute of 35 U.S.C.101 and the utility guideline set forth in the MPEP. Commercial success is only considered as secondary evidence for overcoming a 103 (a) rejection according to guidelines set by MPEP. If Applicant considers the sale of the claimed invention proves the utility and teaches specifically how to use the claimed invention, Applicant is invited to provide case law that validate such statement.

The examiner's statement in the previous 103 rejection was directed to claims with different scope, and this rejection was withdrawn when the claims are amended to the current scope. This statement cannot be relied on for the enablement of the instant claimed invention because it merely provides a reason for making a PTP36 knockout mouse of entirely different scope (without the limitation of the instantly claimed phenotype). The statute requires the

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specification to teach not only how to make but also how to use the claimed invention in such a way that undue experimentation is not required. The specification teaches that the claimed mouse can be used as model for disease or drug screening model. However, the specification fails to teach what type of disease the claimed invention can represent. The specification also fails to teach what type of drug such mouse can screen. As such, the PTP36 knockout mouse with claimed phenotype is not a valid model for any human disease. The examiner cannot agree with Applicant's assertion that each disclosed phenotype is correlated with a disorder that is observed in humans because such genotypic and phenotypic correlation as claimed is not known in any human disorder. Applicant gives the example that increased body weight is related to obesity and diabetes. However, the prior art teaches that diabetes and obesity are caused multiple factors which have nothing to do with the function of PTP36 gene. Moreover, the claimed mouse must exhibit additional symptoms such as increased blood glucose level and insulin intolerance, the primary symptoms of human diabetes, for it to be a valid model of diabetes. The specification does not teach such phenotype in the claimed mouse. In addition, the specification also fails to teach what type of reproductive abnormalities is associated with the specific uterine abnormality observed in these mice. As such, the specification fails to enable the claimed invention because it does not teach specifically how to use the claimed invention with these embodiment.

In response to Applicant's argument regard *In re Brana*, the examiner does not agree that it applies in the instant case. Applicant has taken one conclusion out of the context. Although the case law states "Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development," it is

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referring to a chemical compound for its anti-tumor activity which has been demonstrated in tumor cell line. The specification of that application has taught a substantial and specific use for the claimed compound. However, in the instant case, the claimed knockout mouse does not have a specific and substantial use since the specification does not teach credibly what disease model the claimed mouse represents and/or what type of drug the claimed mouse can screen. As discussed above, the utility of studying the function of the PTP36 is an invitation of further research in which the function of the claimed invention is not known. Therefore, one skilled in the art would not know how to use the claimed invention according to the embodiments disclosed by the instant specification. The rejection is thus maintained.

Newly added claim 52 is also rejected under 35 U.S.C. 112 1<sup>st</sup> paragraph because one skilled in the art would not know how to use a transgenic mouse without any phenotype for same reasons as set forth in the previous office action (for detailed reason, see page 6 of the office action mailed on 6/3/03).

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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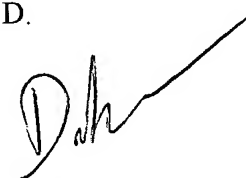
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.  
Examiner  
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DAVE T. NGUYEN  
PRIMARY EXAMINER